

BLEMISH CORRECTING SERUM- benzoyl peroxide gel
CEN BEAUTY LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

ACTIVE INGREDIENT

BENZOYL PEROXIDE 5%

PURPOSE

ACNE TREATMENT

USES

- TREATS ACNE
- DRIES UP ACNE PIMPLES
- HELPS PREVENT NEW ACNE PIMPLES

WARNINGS

FOR EXTERNAL USE ONLY

DO NOT USE

- IF YOU HAVE VERY SENSITIVE SKIN
- ARE SENSITIVE TO BENZOYL PEROXIDE

WHEN USING THIS PRODUCT

- AVOID UNNECESSARY SUN EXPOSURE AND USE A SUNSCREEN
- AVOID CONTACT WITH THE EYES, LIPS, AND MOUTH. AVOID CONTACT WITH HAIR AND DYED FABRICS, WHICH MAY BE BLEACHED BY THE PRODUCT.
- SKIN IRRITATION MAY OCCUR, CHARACTERIZED BY REDNESS, BURNING, ITCHING, PEELING, OR POSSIBLY SWELLING. IRRITATION MAY BE REDUCED BY USING THE PRODUCT LESS FREQUENTLY OR IN A LOWER CONCENTRATION.
- SKIN IRRITATION AND DRYNESS IS MORE LIKELY TO OCCUR IF YOU USE ANOTHER TOPICAL ACNE MEDICATION AT THE SAME TIME.
- IF IRRITATION OCCURS, ONLY USE ONE TOPICAL ACNE MEDICATION AT A TIME.

STOP USE AND ASK A DOCTOR IF TOO MUCH SKIN IRRITATION OR SENSITIVITY DEVELOPS OR INCREASES.

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DIRECTIONS

- ON CLEAN AND DRY SKIN, APPLY A SMALL AMOUNT EVENLY OVER THE AFFECTED AREAS.
- AVOID THE DELICATE EYE AREA.
- START WITH ONE APPLICATION DAILY THEN GRADUALLY INCREASE TO TWO TIMES DAILY IF NEEDED, OR AS DIRECTED BY A DOCTOR.
- IF BOTHERSOME DRYNESS OR PEELING OCCURS, REDUCE APPLICATION TO ONCE A DAY OR EVERY OTHER DAY.
- CONSULT A PHYSICIAN BEFORE USE.

Other Information

Store at 15-30°C (59-86°F)

INGREDIENTS

aqua (water), diglycerin, propanediol, butylene glycol, salicylic acid, allantoin, bisabolol, glycerin, angelica sinensis extract, avena sativa (oat) kernel extract, lecithin, ethylhexylglycerin, carbomer, acrylates/C10-30 alkyl acrylate, crosspolymer, aminomethyl propanol, phenoxyethanol, potassium sorbate

<p>Drug Facts</p> <hr/> <table border="0"> <tr> <td style="width: 60%;">Active ingredient</td> <td style="text-align: right;">Purpose</td> </tr> <tr> <td>Benzoyl Peroxide 5%.....</td> <td style="text-align: right;">Acne Treatment</td> </tr> </table>	Active ingredient	Purpose	Benzoyl Peroxide 5%.....	Acne Treatment	<p>Drug Facts (continued)</p> <hr/> <p>Directions</p> <ul style="list-style-type: none"> ▪ On clean and dry skin, apply a small amount evenly over the affected areas. ▪ Avoid the delicate eye area. ▪ Start with one application daily then gradually increase to two times daily if needed, or as directed by a doctor. ▪ If bothersome dryness or peeling occurs, reduce application to once a day or every other day. ▪ Consult a physician before use.
Active ingredient	Purpose				
Benzoyl Peroxide 5%.....	Acne Treatment				
<p>Uses</p> <ul style="list-style-type: none"> ▪ Treats acne ▪ Dries up acne pimples ▪ Helps prevent new acne pimples 					
<p>Warnings</p> <p>For external use only</p> <hr/> <p>Do not use</p> <ul style="list-style-type: none"> ▪ If you have very sensitive skin ▪ Are sensitive to Benzoyl Peroxide 	<p>Other Information</p> <ul style="list-style-type: none"> ▪ Store at 15-30°C (59-86°F) 				
<p>When using this product</p> <ul style="list-style-type: none"> ▪ Avoid unnecessary sun exposure and use a sunscreen ▪ Avoid contact with the eyes, lips, and mouth. Avoid contact with hair and dyed fabrics, which may be bleached by this product ▪ Skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration ▪ Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. ▪ If irritation occurs, only use one topical acne medication at a time. 	<p>Inactive Ingredients aqua (water), diglycerin, propanediol, butylene glycol, salicylic acid, allantoin, bisabolol, glycerin, angelica sinensis extract, avena sativa (oat) kernel extract, lecithin, ethylhexylglycerin, carbomer, acrylates/C10-30 alkyl acrylate, crosspolymer, aminomethyl propanol, phenoxyethanol, potassium sorbate</p>				
<p>Stop use and ask a doctor if too much skin irritation or sensitivity develops or increases.</p> <hr/> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>					



CLEAR

BLEMISH
CORRECTING
SERUM

1 fl oz 30ml e

BLEMISH CORRECTING SERUM

benzoyl peroxide gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54272-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIGLYCERIN (UNII: 3YC120743U)	

PROPANEDIOL (UNII: 5965N8W85T)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
ALLANTOIN (UNII: 344S277G0Z)	
.ALPHA.-BISABOLOL, (+/-)- (UNII: 36HQN158VC)	
GLYCERIN (UNII: PDC6A3C0OX)	
ANGELICA SINENSIS WHOLE (UNII: 697D19QDBN)	
GLYCERIN (UNII: PDC6A3C0OX)	
ANGELICA SINENSIS WHOLE (UNII: 697D19QDBN)	
AVENA SATIVA TOP (UNII: 1ZX4OXU3N6)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CARBOMER 934 (UNII: Z135WT9208)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54272-102-11	30 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	02/21/2013	

Labeler - CEN BEAUTY LLC (078664118)

Registrant - CEN BEAUTY LLC (078664118)